

510(k) Summary

K101990

Company Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact Donovan May
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
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Date Prepared July 14, 2010

Device Name Trade Name: Ethicon Endo-Surgery Generator G11
Common Name: Electrosurgical & Ultrasonic Surgical Generator

Classification Names

- Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)
- Electrocautery, Gynecologic and Accessories (21 CFR 884.4120, Product Code HGI)
- Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Predicate Devices

- EnSeal® RF60 Electrosurgical Generator (cleared under K072177 on September 5, 2007 as part of the EnSeal® Vessel Sealing and Hemostasis System)
- EnSeal® Universal Generator (cleared under K081129 on July 28, 2008 as a system with the EnSeal PowerTip instrument)
- UltraCision Harmonic® Scalpel Generator 300 (cleared under K002906 on December 15, 2000 as part of the UltraCision Harmonic® Scalpel Generator 300 System)

Device Description:

The Ethicon Endo-Surgery Generator G11 supplies energy to EnSeal® electrosurgical instruments and Harmonic® ultrasonic surgical instruments. The generator utilizes a touchscreen display interface and has a receptacle port that accepts either EnSeal® or Harmonic® devices. Connectors (one for Harmonic® and one for EnSeal® instruments) are used to enable the generator to power currently cleared surgical instruments.

Indications for Use:

The Generator G11 provides radiofrequency power to drive EnSeal® electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissue. In addition the generator provides power to drive Harmonic® ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

EnSeal® and Harmonic® instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

The differences between the intended use of the subject device and those of the predicate devices do not affect the safety and effectiveness of the subject device when used as labeled for the following reasons:

- The Generator G11 provides power for the use of both EnSeal electrosurgical and Harmonic ultrasonic surgical open and laparoscopic surgical instruments. The predicate devices referenced are only able to provide power for one of these surgical instrument types.
- The predicate devices were each submitted as part of a surgical system thus the Indications for Use statements included in the submissions associated with them did not contain indications specific to the function of the generators except for those in the labeling. These differences do not alter the intended surgical effects of the subject device from that of the predicate devices.

Technological Characteristics: The Ethicon Endo-Surgery Generator G11 incorporates the technological characteristics of the predicate devices in a single surgical generator but allows for a greater range of power, voltage, current, and frequency for both the EnSeal electrosurgical and Harmonic ultrasonic surgical modes. A touchscreen user interface has been incorporated to provide the user with information, control, and feedback during use.

Performance Data: Bench testing and laboratory evaluations in an animal model were conducted to demonstrate that the Generator G11 performs as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Mr. Donovan May
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

JUN 13 2011

Re: K101990

Trade Name: Generator G11
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, LFL, HGI
Dated: June 1, 2011
Received: June 2, 2011

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101990

Device Name: Generator G11

Indications for Use:

The Generator G11 provides radiofrequency power to drive EnSeal[®] electro-surgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissue. In addition the generator provides power to drive Harmonic[®] ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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